

Regulating patient safety during hospital discharges: Casting the Patient Safety Commissioner as the Representative of Order

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Abstract

This article examines the challenges in regulating patient safety during hospital discharges in England through the lens of liminality. Hospital discharges are internationally recognised as being a dangerous time for patients, and yet the role that regulators should play in addressing this has received little attention in any jurisdiction. Liminality's spotlight on the in-between highlights how the discharge process can give rise to patient safety incidents that fall between regulator's boundaries. Falling between boundaries results in a dearth of effective regulatory responses to address these incidents. By positioning the new role of Patient Safety Commissioner (PSC) as that of a 'Representative of Order', this article proposes a means by which this poorly regulated space could be navigated more successfully. This analysis suggests that the remit of the PSC role be expanded to include improving patient safety with regard to processes – not just medicines and medical devices. The full implications of this are also addressed.

Keywords

Patient safety, regulation, hospital discharges, liminality, IMMDS review, Medicines and Medical Devices Act

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Introduction: Understanding patient safety and hospital discharges

We have found that the healthcare system – in which I include the NHS, private providers, the regulators and professional bodies, pharmaceutical and device manufacturers, and policymakers – is disjointed, siloed, unresponsive and defensive. It does not adequately recognise that patients are its *raison d'être*. It has failed to listen to their concerns and when, belatedly, it has decided to act it has too often moved glacially.¹

The above sums up the findings of the Independent Medicines and Medical Devices Safety (IMMDS) review in England, published in 2020. The Review's purpose was to examine how the English² healthcare system responded to concerns raised about harmful side effects from specific medicines and medical devices³ and to consider how future responses to concerns over side effects could be quicker and more effective.⁴ That the healthcare system is disjointed and siloed⁵ is a problem that significantly contributes to the harm patients experience when discharged from hospital; a problem that regulators have thus far failed to adequately address.⁶ In an earlier article,⁷ I drew attention to how risk-based regulation, a prominent model of regulation within the English NHS, is poorly equipped to ensure and improve patient safety in this regard.

This article employs the anthropological concept of liminality as a lens through which to view these challenges in regulating patient safety during hospital discharges. Although this article focusses upon the English context, patients are internationally recognised as being at an increased risk of harm when leaving hospital.⁸ The rationale for using

1. Independent Medicines and Medical Devices Safety Review, (2020) *First Do No Harm: The Report of the Independent Medicines and Medical Devices Safety Review*, p.i. Available at: https://www.immndsreview.org.uk/downloads/IMMDSReview_Web.pdf (accessed 1 June 2021).
2. Although the review focussed on England its recommendations cover England only, evidence was heard from across the United Kingdom (Op. Cit. paras 1.9 and 1.10).
3. These were hormone pregnancy tests, sodium valproate and pelvis mesh implants.
4. IMMDS Review, 'First Do No Harm'.
5. Siloed working refers to instances where organisations take a non-collaborative approach to work. NHS England has acknowledged that it works in 'silos'. Available at: <https://www.england.nhs.uk/blog/rolling-up-our-sleeves-and-getting-out-of-our-silos/> (accessed 1 June 2021).
6. V. Moore, 'Leaving Hospital: A step too far for risk-based regulation?', 28 *Medical Law Review* (2020), pp. 675–695.
7. Op. cit.
8. K. Aase and others, *Researching Quality in Care Transitions International Perspectives* (London: Palgrave Macmillan, 2017); K. Manges and others, 'A Mixed Methods Study Examining Teamwork Shared Mental Models of Interprofessional Teams During Hospital Discharge', *BMJ Quality & Safety* 0 (2019), pp. 1–10; World Health Organisation, *Transitions of Care: Technical Series on Safer Primary Care*. (2016) Available at: https://www.who.int/patientsafety/topics/primary-care/technical_series/en/ (accessed 1 June 2021).

liminality in this particular area is because it brings into focus the in-between space that exists among regulatory bodies (this is explained more fully below).

The discharge process is subject to multiple regulatory requirements and influences. However, if a patient safety incident occurs in relation to this process and does not fall squarely within any regulator's remit, then it may end up within a regulatory lacuna. This we might usefully conceive of as a liminal space, and this article addresses the implications of this conceptualisation for regulating patient safety in hospital discharge. Using liminality, this article has two central aims. First, it seeks to illustrate this space in-between regulators. Secondly, it argues that the creation of a new Patient Safety Commissioner (PSC) role could be one way in which to improve patient safety during hospital discharges. The creation of a PSC was recommended by the IMMDS review⁹ and established in the new Medicines and Medical Devices Act 2021 (MMD Act).¹⁰ At the time of writing, there is no indication of when the first commissioner will be appointed. It is proposed herein that the remit of the PSC be extended beyond medicines and medical devices to include improving patient safety with regard to *processes*, such as hospital discharges.

The remainder of this introduction outlines the nature of the risks that hospital discharge can pose to the safety of patients. The second section details the actors within the hospital discharge regulatory arena and draws attention to how they have attempted to engage in this space thus far. The third section introduces the concept of liminality, and illustrates the liminal space within this context. It shows how this space occurs as a result of the plethora of regulators and the related challenge of forming a unified understanding and prioritisation of the risk posed by hospital discharges.¹¹ Actions then taken to improve safety during discharges (typically the production of a report) often fail to have the desired impact. To minimise this undesirable occurrence, this article envisages that the new PSC role could function as a Representative of Order. The rationale for this is explored in the fourth section, and the example of another Representative of Order within the patient safety field – the Chief Coroner – is used to demonstrate how such a role can improve safety. The fifth section incorporates learning from this example to illustrate how the PSC, when cast as a Representative of Order, could help regulators overcome the difficulties identified in the third section.

Patient safety and hospital discharges

Common problems highlighted in a 2016 report by the Parliamentary and Health Service Ombudsman (PHSO) relate to patients being discharged before it is clinically safe to do so; failing to involve patients and their families/carers in decision-making surrounding discharge; and discharging patients despite no appropriate ongoing support being in place.¹² These issues have become increasingly apparent during the COVID-19

9. IMMDS Review, 'First Do No Harm', Recommendation 2.

10. Medicines and Medical Devices Act 2021, section 1.

11. Moore, 'Leaving Hospital'.

12. Parliamentary and Health Service Ombudsman, *A Report of Investigations into Unsafe Discharge from Hospital* (PHSO 2016). Available at: <https://www.ombudsman.org.uk/publications/report-investigations-unsafe-discharge-hospital-0> (accessed 1 June 2021).

pandemic. For example, MIND (a mental health charity in England and Wales) expressed concern that people may have been discharged from mental health hospitals when it was unsafe to do so or without adequate support.¹³ It noted that in April 2020, only 4030 discharges were followed up within 72 h, out of 5571 that were eligible for follow-up.¹⁴ Based on interviews with patients/carers regarding discharge between March and August 2020, Healthwatch England (HE) and the British Red Cross reported that basic checks such as whether people needed transport to get home were missed.¹⁵ People reported feeling unprepared to leave hospital and confused about who could be contacted for further information. Several reported not receiving any follow-up assessments after discharge, which meant they did not have the medication or equipment needed to recover properly in their home.¹⁶

A study of data¹⁷ on discharge-related safety incidents within England's National Reporting and Learning System database¹⁸ found four main categories of error that caused harm to patients in 75% of the cases studied. These were quality of discharge communication, referrals to community care, medication errors, and issues concerning the provision of care adjuncts (such as wound dressings) for ongoing community care. Behavioural factors, for example where staff did not follow protocols, and organisational factors such as a lack of clear guidelines, also contributed to safety incidents. Although the severity of harm tended to be low-level,¹⁹ in 78 cases (13%), patients experienced moderate harm. This meant patients required an intervention to resolve their symptoms and may have experienced permanent/long-term harm or a loss of function. In three (<1%) severe cases, life-saving interventions were needed, and in one case the patient died.²⁰

An ethnographic study by Waring and colleagues found that the coordination of multiple actors across occupational and organisational boundaries and the interdependencies and interactions between these groups can represent a threat to discharge safety.²¹ The study identified the following issues between healthcare settings which the authors suggest might explain the variations in discharge safety. First, differences in

13. MIND, 'The Impact of Coronavirus on Discharge from Mental Health Hospital', Available at: <https://www.mind.org.uk/media-a/6293/the-impact-of-coronavirus-on-mental-health-hospital-discharge-briefing.pdf> (accessed 1 June 2021).

14. Op. cit.

15. Healthwatch England and British Red Cross (2020), '590 people's stories'.

16. Op. cit.

17. H. Williams, and colleagues, 'Harms from Discharge to Primary Care: Mixed Methods Analysis of Incident Reports', *British Journal of General Practice* 65 (2015), pp. e829–e837.

18. The NRLS is a central database of patient safety incidents reported from across England and Wales.

19. 'Low-level' was defined by the study authors as patients experienced mild symptoms, the harm was short-term, and little or no intervention was required to resolve the harm.

20. Williams, 'Harms from Discharge', pp. e829–e837.

21. J. Waring, F. Marshall and S. Bishop, 'Understanding the Occupational and Organizational Boundaries to Safe Hospital Discharge', *Journal of Health Services Research & Policy* 20 (2015), pp. 35–44.

organisation (such as how technologies are used and how labour is divided); secondly, culture (whether there is a blame culture, the extent to which patients are involved in their care); and thirdly, knowledge (e.g. how discharge is understood across each group of professionals).²² The authors conclude that increased use of ‘boundary spanners’ may be one way to improve patient safety during discharges. Boundary spanners are actors who work across occupational and organisational boundaries and so are often able to learn about cultures, knowledge, and ways of working that may not be accessible to actors working in professional silos.²³ This suggests that in complex regulatory environments, there is a role for a designated actor to guide people through – a point that has been well made by Laurie and colleagues.²⁴

Alongside experiencing physical harm, patients’ dignity may also be harmed during hospital discharges.²⁵ According to the NHS Constitution (which is enshrined in the 2009 Health Act),²⁶ patients have a right to be treated with dignity and respect in accordance with their human rights. Although dignity is not explicitly defined in law, thus making a requirement to respect human dignity difficult for regulators to enforce,²⁷ it is nevertheless an important part of patient safety.²⁸ Patients view non-clinical incidents as a safety incident; and dignity featured in one study as a patient-derived safety category.²⁹ The PHSO report into unsafe discharges gives the example of Mrs K, an elderly person with dementia who was discharged late at night unbeknownst to her family. She was found at home by her daughter the next day, without food, drink, or bedding and had been unable to get to her toilet.³⁰ We can imagine that Mrs K may have experienced this incident as an affront to her dignity and well-being. Having illustrated the wide-ranging factors that may pose a serious threat to patients’ safety and dignity when leaving hospital, we now turn attention to matters of regulation.

Regulation and hospital discharges

Oikonomou and colleagues define healthcare regulation as ‘the processes engaged in by institutional actors that seek to shape, monitor, control or modify activities within healthcare organisations in order to reduce the risk of patients being harmed during their

22. Op. cit.

23. Op. cit.

24. G. Laurie et al., ‘Charting Regulatory Stewardship in Health Research: Making the Invisible Visible?’, *Cambridge Quarterly of Healthcare Ethics* 27 (2018), pp. 333–347.

25. Moore, ‘Leaving Hospital’.

26. National Health Service, (2015) ‘NHS Constitution for England’.

27. T. Caulfield and R. Brownsword, ‘Human Dignity: A Guide to Policy Making in the Biotechnology Era?’, *Science and Society* 7 (2006), pp. 72–76.

28. Moore, ‘Leaving Hospital’.

29. J.K. O’Hara and colleagues, ‘What can Patients Tell us about the Quality and Safety of Hospital Care? Findings from a UK Multicentre Survey Study’, *BMJ Quality & Safety* 27 (2018), pp. 673–682.

30. PHSO, ‘Investigations into Unsafe Discharge’, p. 19.

care'.³¹ This broad definition captures a wide range of behavioural influences performed by several actors within a healthcare system. It is perhaps a welcome definition in that it broadness allows a wide variety of institutions to be compared.³² However, Walshe argues that it is important to set sensible boundaries around the concept of regulation as broad interpretations risk the concept becoming 'almost meaningless'.³³ According to Black, definitional vagueness is generally seen by those writing on regulation as, 'at best a rather quaint feature and at worst an occupational hazard'.³⁴ She does, however, indicate that some clarity is needed to avoid confused debate regarding what regulation should or should not be and observes that academics lack a disciplined approach to defining regulation.³⁵ Its conceptualisation, she argues, often depends upon the issue that the writer is focused upon.³⁶ Against this backdrop of 'definitional chaos',³⁷ this article uses the term 'regulation' to refer to the formal attempts by statutory regulators to shape behaviour within healthcare organisations. This is inspired by Black's definition of regulation as 'the sustained and focused attempt to alter the behaviour of others according to defined standards or purposes with the intention of producing a broadly identified outcome or outcomes'.³⁸ The focus is narrowed in this article to statutory regulators because these have a legal duty to protect patients and are therefore the ones who should be held accountable for any regulatory failings that are uncovered. That said, this narrower focus is not intended to dismiss any other actors which exert regulatory influence; rather it takes the view that other actors have an important role to play in feeding into the actions undertaken by the statutory regulators as they seek to improve safety. Such a position is cohesive with both the findings of the IMDDS review³⁹ and Quick's view that regulating patient safety requires regulation to be seen as a collaboration between patients and professionals, and this in turn means that the involvement of patients is both necessary and legitimate.⁴⁰

This article uses the term 'regulatory arena' to refer to the regulatory environment within which regulation takes place. A more common term is 'regulatory space' – coined by Hancher and Moran.⁴¹ 'Arena' is used here to minimise any confusion between this

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31. E. Oikonomou and colleagues, 'Patient Safety Regulation in the NHS: Mapping the Regulatory Landscape of Healthcare', *BMJ Open* 9 (2019), p. 2.
 32. T. Prosser, *The Regulatory Enterprise: Government, Regulation, and Legitimacy* (Oxford: OUP, 2010).
 33. K. Walshe, *Regulating Healthcare: A Prescription for Improvement* (Maidenhead: OUP, 2003), p. 10.
 34. J. Black, 'Critical Reflections on Regulation', *Australian Journal of Legal Philosophy* 27 (2002), p. 11.
 35. Op. cit.
 36. Op. cit.
 37. Op. cit. p. 11.
 38. J. Black, 'Decentering Regulation: Understanding the Role of Regulation and Self-Regulation in a Post-Regulatory World', *Current Legal Problems* 54 (2001), p. 142.
 39. IMDDS Review, 'First Do No Harm'.
 40. O. Quick, *Regulating Patient Safety* (Cambridge: CUP, 2017), p. 164.
 41. L. Hancher and M. Moran, 'Organizing Regulatory Space', in L. Hancher and M. Moran, eds., *Capitalism, Culture and Economic Regulation* (Oxford: OUP, 1989), pp. 271–300.

and the concept of ‘liminal space’ which will shortly be introduced. Conceptually, the regulatory arena is intended here to be the same as the regulatory space. The ‘regulatory space’ refers to the environment within which regulation takes place; which includes the actors within it, alongside wider factors such as the legal system, sociocultural influences and the relationship dynamics between actors.⁴² Rather than flowing hierarchically, power and influence within the regulatory arena can be exercised horizontally and vertically by actors seeking to modify the behaviour of each other,⁴³ creating what Morgan and Yeung refer to as a ‘reflexive process of influence and change within the regulatory space’.⁴⁴ Regulatory arenas can be defined broadly⁴⁵ and narrowly. A broad definition might be employed when considering all impacts upon patient safety within the English NHS; however, this article narrows focus towards the concerning hospital discharges within the English NHS. This arena involves not only statutory regulators, but multiple others with a shared aim of patient safety at the point of discharge.

The hospital discharge regulatory arena

This section identifies the actors within this regulatory arena operating at a national level and their actions in this setting. The purpose of this mapping⁴⁶ is to bring to attention the vast number of actors, not all of which are statutory regulators, that have made attempts to respond to the serious patient safety issues posed by discharges. It will then be argued that weaknesses within risk-based regulation result in regulators creating thresholds which must be met in order for them to take action in response to a particular risk. Where their conceptualisation of the risk then fails to meet their own threshold, the regulator’s response is likely to be inaction.

Before focussing upon the statutory regulators, influential non-regulatory actors will be briefly introduced. Patient voices are represented within the arena through the PHSO, patient groups and charities. The PHSO makes the final decision on complaints that have not been resolved by the NHS in England.⁴⁷ As mentioned earlier, in 2016 the PHSO published a report into unsafe discharges, based upon the complaints it had received (more will be said on this report in section three).⁴⁸ HE, a statutory committee of the Care Quality Commission (CQC), escalates concerns raised by local Healthwatch

42. E. Windholz, *Governing through Regulation: Public Policy, Regulation and the Law* (Abingdon: Routledge, 2018), p. 71.

43. Op. cit. p. 71.

44. B. Morgan and K. Yeung, *An Introduction to Law and Regulation* (Cambridge: CUP, 2007), p. 76.

45. Windholz, ‘*Governing through Regulation*’, pp. 70–72.

46. For further ‘mapping’ of regulatory actors within the NHS, see also D. Horton and G. Lynchwood, ‘Technocracy, the Market, and the Governance of England’s National Health Service’, *Regulation and Governance* 14 (2020), pp. 295–315; D. Horton, ‘Rhetoric and Reality: User Engagement and Health Care Reform in England’ *Medical Law Review* 26 (2018), pp. 27–50; and E. Oikonomou et al, ‘Patient safety regulation in the NHS’.

47. Available at: <https://www.ombudsman.org.uk/> (accessed 1 June 2021).

48. PHSO, ‘Investigations into Unsafe Discharge’.

organisations to the CQC;⁴⁹ HE has produced three reports on unsafe hospital discharges since 2015.⁵⁰ Charities also seek to influence the regulatory arena by sharing patients' experiences; for example, the British Red Cross and Patients Association have both published findings of people's experiences of hospital discharge.⁵¹ The National Institute for Health and Care Excellence (NICE) provides evidence-based guidance to help health and social care professionals deliver the best possible care.⁵² In 2015, NICE published its guideline on the transition between inpatient hospital settings and community or care homes for adults with social care needs.⁵³ Although guidelines are not legally binding, failing to follow NICE guidelines may lead to legal consequences.⁵⁴

Hospital discharges involve the coordination of numerous actors across occupational and organisational boundaries.⁵⁵ All of these actors are subject to different regulatory

49. Available at: <https://www.healthwatch.co.uk/our-history-and-functions> (accessed 1 June 2021).
50. Healthwatch England, 'Safely Home: What Happens when People Leave Hospital and Care Settings?' (2015). Available at: <https://www.healthwatch.co.uk/report/2015-07-21/safely-home-what-happens-when-people-leave-hospital-and-care-settings> (accessed 1 June 2021); Healthwatch England, 'What Happens when People Leave Hospital and other Care Settings?', (2017). Available at: <https://www.healthwatch.co.uk/report/2017-10-05/what-happens-when-people-leave-hospital-and-other-care-settings> (accessed 1 June 2021); Healthwatch England, 'Emergency Readmissions: What's Changed One Year On?' (2018). Available at: <https://www.healthwatch.co.uk/report/2018-11-14/emergency-readmissions-whats-changed-one-year> (accessed 1 June 2021).
51. British Red Cross, 'In and Out of Hospital', (2018). Available at: <https://www.redcross.org.uk/about-us/news-and-media/media-centre/press-releases/press-release-repeat-visits-to-accident-and-emergency> (accessed 1 June 2021); British Red Cross, 'Home to the Unknown: Getting Hospital Discharge Right', (2019). Available at: www.redcross.org.uk/about-us/what-we-do/we-speak-up-for-change/more-support-when-leaving-hospital/getting-hospital-discharge-right (accessed 1 June 2021); Healthwatch England and British Red Cross, '590 People's Stories of Leaving Hospital During Covid-19', (2020). Available at: <https://www.healthwatch.co.uk/report/2020-10-27/590-peoples-stories-leaving-hospital-during-covid-19> (accessed 1 June 2021); Patients Association, 'Premature Discharge from Hospital', (2020). Available at <https://www.pslhub.org/learn/patient-engagement/keeping-patients-safe/premature-discharge-from-hospital-june-2020-r2568/> (accessed 1 June 2021).
52. Available at: <https://www.nice.org.uk/about/who-we-are/our-charter> (accessed 1 June 2021).
53. NICE, 'Transition Between Inpatient Hospital Settings and Community or Care Home Settings for Adults with Social Care Needs', (2015). Available at: <https://www.nice.org.uk/guidance/ng27> (accessed 1 June 2021).
54. A. Samanta et al, 'The Role of Clinical Guidelines in Medical Negligence Litigation: A Shift from the Bolam Standard?', *Medical Law Review* 14 (2006). pp. 321–366; *R (on the application of Elizabeth Rose) v Thanet Clinical Commissioning Group* [2014] EWHC 1182 (Admin); *R v North Derbyshire Health Authority* [1997] EWHC Admin 675; J. Bleasdale, 'NICE Guidelines: Not Just the Gold Standard Practice', (2018). Available at: <https://www.hilldickinson.com/insights/articles/nice-guidelines-not-just-gold-standard-practice> (accessed 1 June 2021).
55. Waring, 'Occupational and Organizational Boundaries'.

regimes. Professional regulators such as the General Medical Council (GMC), Nursing and Midwifery Council, Health and Care Professions Council, General Pharmaceutical Council, and Social Work England regulate the healthcare professionals working within healthcare. Each of the professional regulators⁵⁶ set standards of behaviour, competence and education that professionals must meet; these are expressed within the professionals' codes. Hospital discharges are not directly mentioned in the codes; however, behaviours and skills relevant to ensuring safe discharge (such as communication and record-keeping) are specified.⁵⁷ The systems within which these healthcare professionals work are not regulated by the same regulatory bodies; meaning there is a regulatory split between people and their work environment. Writing on human error, Reason argues that by focusing on the individual as an origin of error, unsafe acts become isolated from their system context.⁵⁸ Although not in scope for this article, this raises an interesting question regarding whether merging regulators to create one responsible for overseeing both professionals and their working environment would be effective.

The CQC, NHS England (NHSE), and NHS Improvement (NHSI) regulate the system and environment within which healthcare professionals work; each has statutory duty pertaining to patient safety. The CQC was established under the Health and Social Care Act 2008 with a primary objective to protect and promote the health, safety and welfare of people using health and social care services.⁵⁹ As the regulator of the quality of health and social care in England, the CQC has an assessment framework that it applies to the regulation of all health services. During its inspections of services, the CQC asks questions relating to the safety, effectiveness and responsiveness of hospital discharges.⁶⁰ In 2018, the CQC's annual adult inpatient survey report flagged hospital discharge planning as an area for improvement.⁶¹ In 2019, the same annual survey showed 'continuing patterns of decline' regarding care coordination at discharge.⁶² For example, the survey highlighted how two in five people had not been given any printed information on what they should do after leaving hospital – which was a decline of seven percentage points

56. There are nine bodies tasked with overseeing the regulation of healthcare professionals in England: GMC, GDC, GCC, GOC, GOsC, GPHC, HCPC, NMC, SWE.

57. For example, see paragraph 1 of the NMC's Code (2015); standard 1 of 'Standards for Pharmacy Professionals' (2017); section 2.2 of Social Work England's Professional Standards (2019), and paragraph 25 of the GMC's 'Good Medical Practice'. The GMC's 'Good practice in prescribing and managing medicines and devices' (2021) also states in paragraph 53 that doctors must contribute to the safe transfer of patients.

58. J. Reason, 'Human Error: Models and Management', *British Medical Journal* 320(7237) (2000), pp. 768–770.

59. Health and Social Care Act 2008, section 3(1).

60. CQC, 'Key Lines of Enquiry, Prompts and Ratings Characteristics for Healthcare Services'. (2018). Available at: <https://www.cqc.org.uk/sites/default/files/20180628%20Healthcare%20services%20KLOEs%20prompts%20and%20characteristics%20FINAL.pdf> (accessed 1 June 2021).

61. CQC, '2018 Adult Inpatient Survey: Statistical Release', (2019). Available at: https://www.cqc.org.uk/sites/default/files/20190620_ip18_statisticalrelease.pdf. (accessed 1 June 2021).

62. CQC, '2019 Adult Inpatient Survey: Statistical Release', (2020). p. 54. Available at:

since 2013. This result was ‘lower than where [the CQC] would expect, based on past data, the fourth consecutive year’.⁶³

NHSE has a duty to improve the quality and safety of services provided to patients.⁶⁴ With regard to hospital discharge safety, the organisation has produced a series of guides intended to support local systems in reducing the time people spend in hospital. The stated aim is not to encourage inappropriate discharges but to improve safety, given evidence that longer hospital stays can be associated with poorer health outcomes.⁶⁵ In 2014, NHSE issued a patient safety alert to NHS organisations stressing the importance of appropriately communicating essential information when discharging patients. Failures to do so had resulted in ‘avoidable death and serious harm to patients due to a failure in continuity of care as well as avoidable readmission to secondary care’.⁶⁶ NHSE works jointly with NHSI,⁶⁷ which also has a statutory duty to protect and promote the interests of people using health care services.⁶⁸ As the COVID-19 pandemic took hold, the government and NHSE issued guidance to hospitals with the aim of freeing up bed spaces for anticipated patients through accelerating discharges from hospital.⁶⁹ This drive saw 25,000 patients discharged into care homes without being tested prior to discharge for COVID (routine testing was introduced mid-April 2020).⁷⁰ These discharges into care homes took place despite evidence that the policy was fuelling outbreaks of the virus and deaths in care homes;⁷¹ a policy decision described as ‘reckless and negligent’ by the Public Accounts Commit-

63. *Op. cit.* p. 50.

64. National Health Service Act 2006 (as amended by the Health and Social Care Act 2012), section 13E.

65. Available at: <https://www.england.nhs.uk/urgent-emergency-care/improving-hospital-discharge/quick-guides/> (accessed 1 June 2021)..

66. NHS England, ‘Patient Safety Alert NHS/PSA/W/2014/014’. (2014). Available at: <https://www.england.nhs.uk/wp-content/uploads/2014/08/psa-imp-saf-of-discharge.pdf> (accessed 1 June 2021).

67. As of April 2016, NHS Improvement is the operational name for the body that brings together Monitor, NHS Trust Development Authority, NHS England’s Patient Safety teams, the National Reporting and Learning System, the Advancing Change team and the Intensive Support Teams

68. Health and Social Care Act 2012, Part 3 (62)(1).

69. HM Government & NHS England, ‘COVID-19 Hospital Discharge Service Requirements’. Available at https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/880288/COVID-19_hospital_discharge_service_requirements.pdf (accessed 1 June 2021).

70. Public Accounts Committee, ‘Readying the NHS and Social Care for the COVID-19 peak’ (2020), paragraphs 9–11, Available at: https://publications.parliament.uk/pa/cm5801/cmselect/cmpubacc/405/40506.htm#_idTextAnchor012 (accessed 1 June 2021).

71. ‘Discharging coronavirus patients into care homes is ‘madness’, Government told’, *The Telegraph*, 15 April 2020, Available at: <https://www.telegraph.co.uk/news/2020/04/15/discharging-coronavirus-patients-care-homes-madness-government/> (accessed 1 June 2021).

tee.⁷² One in five directors of adult social services expressed concern that the policy had resulted in people being discharged to services unable to fully meet their needs.⁷³ It is outside of the scope of this particular article to fully explore the implications and long-term consequences of this discharge policy on patient safety; it is, however, an aspect deserving of urgent attention. Thus far, NHSE&I have defended the decision by saying it has always been the case that they want to discharge people who are clinically fit, and staying in hospital could be harmful for the elderly'.⁷⁴

As can be seen from the above exploration of the hospital discharge regulatory arena, there are multiple actors within it which have, over the years, made efforts to try and improve the safety of hospital discharges; however, there has been no unified effort. I have argued elsewhere⁷⁵ that risk-based regulation, a strategy frequently employed by the statutory regulators, is partially to blame. Risk-based regulation is intended to focus a regulator's interventions upon threats which pose the greatest risk to its objectives.⁷⁶ Such approaches were strongly endorsed by the 2005 Hampton Report on the grounds that they were seen as essential for efficiently directing regulatory resources to where they can have maximum impact upon outcomes.⁷⁷ Risk-based frameworks typically have the identification of risk as a starting point and commonly feature an assessment of the likelihood of the risk occurring, and a subsequent ranking of risks based upon these assessments.⁷⁸ Three common weaknesses of risk-based regulation approaches⁷⁹ regarding the identification, conceptualisation and prioritisation of risks to patient safety explain why little action has been taken by statutory regulators within the hospital discharge regulatory arena.

The first weakness in relation to identifying risk arises due to limited information-sharing mechanisms among the multitude of regulators, which means regulators do not have a complete picture of all relevant information.⁸⁰ The numerous regulatory bodies and the limited information-sharing among them give rise to the next problem, which is that achieving a unified understanding of the risk posed by hospital discharges is nigh on

72. Public Accounts Committee, 'Readying the NHS'.

73. Kings Fund, 'How Covid-19 has Magnified Some of social Care's Key Problems', (2020). Available at: <https://www.kingsfund.org.uk/publications/covid-19-magnified-social-care-problems> (accessed 1 June 2021).

74. Public Accounts Committee, 'Readying the NHS'.

75. Moore, 'Leaving Hospital'.

76. A. Beaussier et al, 'Accounting for Failure: Risk-Based Regulation and the Problems of Ensuring Healthcare Quality in the NHS', *Health, Risk & Society* 18 (2016), p. 206.

77. P. Hampton, *Reducing Administrative Burdens: Effective Inspection and Enforcement* (HM Treasury 2005).

78. J. Black and R. Baldwin, 'Really Responsive Risk-based Regulation', *Law and Policy* 32(2) (2010), pp. 181–213.

79. A. Beaussier et al, 'Accounting for Failure'; S. Lloyd-Bostock and B. Hutter, 'Reforming Regulation of the Medical Profession: The Risks of Risk-based Approaches', *Health, Risk and Society* 10(1) (2008), pp. 69–83.

80. Moore, 'Leaving Hospital'.

impossible. Risks become conceptualised by each regulator based upon the information which it holds, and inevitably these conceptualisations will vary across regulators. This in turn impacts the priority the risk is afforded.⁸¹ By utilising risk-based regulation, regulators thus create thresholds which must be reached in order for them to take action. If their conceptualisation of a risk fails to meet their threshold, it will not be perceived as a risk that needs *their particular attention*.

This section has identified the actors within the hospital discharge regulatory arena and their actions to address the patient safety challenge posed by hospital discharges. Despite these efforts, the physical well-being and dignity of patients remains at risk at the point of hospital discharge.⁸² The following section offers an account of why these attempts have failed to significantly improve patient safety during discharge, relying on the concept of liminality that is precisely about navigating uncertain spaces of human experience.

Liminality

Upon observing that people undertake certain rituals when transitioning from one social state to another (such as childhood to adulthood), Van Gennep developed the anthropological concept of 'liminality'.⁸³ These rituals consist of three distinct phases, known as rites of passage, which van Gennep declared universal to all societies.⁸⁴ He argued that their purpose is to reduce the harmful effects that can occur as a result of the disruptive impact that changes of social state can have upon the life of an individual and society.⁸⁵ The three phases are the separation from a previous state (preliminal rites), the transitional stage (liminal rites) and incorporation into the new state (postliminal rites).⁸⁶ Within the transitional, liminal stage, the experience is marked by uncertainty for the subject.⁸⁷

Turner writes that a liminal being is one who is 'betwixt and between the positions assigned and arrayed by law, custom, convention, and ceremonial'.⁸⁸ In these spaces, structure gives way to anti-structure, which is to say that the status quo breaks down into chaos.⁸⁹ A figure known as the 'Master of

81. Op. cit.

82. Op. cit.

83. A. van Gennep, *The Rites of Passage* (Chicago: University of Chicago Press, 1960). Note, van Gennep wrote *The Rites of Passage* in 1909.

84. Op. cit.

85. Op. cit.

86. Op. cit.

87. J. Söderlund and E. Borg, 'Liminality in Management and Organization Studies: Process, Position and Place', *International Journal of Management Reviews* 20 (2018), pp. 880–902; G. Laurie, 'Liminality and the Limits of Law in Health Research Regulation: What are we Missing in the Spaces in-Between?', *Medical Law Review* 25 (2016), pp. 47–72.

88. V. Turner, *The Ritual Process: Structure and Anti-Structure* (New Jersey: Transaction, 1969).

89. Op. cit.

Ceremonies'⁹⁰ or 'Representative of Order'⁹¹ is needed to guide people safely through and out of these liminal states so that they are able to reintegrate into society.⁹² Without them liminality can be permanent⁹³ or result in 'lasting rule by tricksters'⁹⁴ (one who presents themselves as leader for their own gains).

Because of this, liminal spaces can be dangerous.⁹⁵ However, people can also have positive experiences within these spaces as a result of *communitas*⁹⁶ arising among them. Laurie describes this as 'a spontaneous sense of interconnectedness of equals, experiencing the same process together'.⁹⁷ Thomasson cautions that *communitas* stemming out of liminality is unpredictable, and we cannot accurately foretell whether it will result in care towards others or in violent destruction.⁹⁸ More on the implications of this spontaneity and unpredictability within a regulatory context will be discussed later within this article.

Having introduced liminality and the Representative of Order role, the remainder of this section proceeds to explore two things. It considers the liminal space within the regulation of hospital discharges and then examines the presence of 'liminal objects'⁹⁹ (often reports produced within the intention of improving patient safety during discharge) within it. The purpose of this exploration is to demonstrate how the lack of a Representative of Order within this liminal space can cause a regulatory failure in addressing safety during discharges, and how objects which become stuck in a liminal state fail in their aim to improve safety. The fourth and fifth sections will then cast the proposed Patient Safety Commissioner as a Representative of Order to explore how such a figure could address these issues.

90. Op. cit; A. Szokolczai, 'Liminality and Experience: Structuring Transitory Situations and Transformative, *International Political Anthropology* 2 (2009), p. 148.

91. V. Turner, *Dramas, Fields, and Metaphors: Symbolic Action in Human Society* (London: Cornell University Press, 1974); P. Stenner and E. Moreno-Gabriel, 'Liminality and Affectivity: The Case of Deceased Organ Donation', *Subjectivity* 6 (2013), p. 248.

92. G. Laurie, 'Liminality and the Limits of Law', p. 54; B. Thomassen, *Liminality and the Modern: Living Through the In-Between*, (Abingdon: Routledge, 2018); G. Laurie, 'How do We Make Sense of Chaos? Navigating Health Research Regulation through the Liminality of the Brexit Process', *Medical Law International* 18 (2018), pp. 110–134; A. Szokolczai, 'Liminality and Experience: Structuring Transitory Situations and Transformative Events', *International Political Anthropology* 2 (2009), pp. 141–172; A. Horvath, 'The Genealogy of Political Alchemy: The Technological Invention of Identity Change' in A. Horvath, B. Thomassen and H. Wydra, eds., *Breaking Boundaries: Varieties of Liminality* (New York: Berghahn Books, 2015), ch.4.

93. Laurie, 'How do we make sense of chaos?', p. 117.

94. Szokolczai, 'Liminality and experience', p. 157.

95. Op. Cit.

96. Turner, 'The Ritual Process, 1969'.

97. Laurie, 'Liminality and the limits of law', p. 59.

98. Thomasson, 'Liminality and the Modern', p. 84.

99. S. Taylor-Alexander and colleagues, 'Beyond Regulatory Compression: Confronting the Liminal Spaces of Health Research Regulation', *Law, Innovation and Technology* 8 (2016), pp. 149–176.

The liminal space within hospital discharge regulation

The result of the regulatory split between healthcare professionals and systems outlined in the previous section is that hospital discharges are subject to multiple regulatory requirements and influences. A patient safety incident (PSI) which occurs in relation to the hospital discharge process is frequently not a failing on the part of one actor. Indeed, the incidents themselves can be understood as occurring within the liminal spaces of healthcare provision, particularly at the point where different systems meet and interact (interfaces). It has been found that about 50% of medical errors occur at healthcare interfaces, with up to one-third of these arising at the primary–secondary care interface.¹⁰⁰ Incidents resulting from a complex interaction between professionals and the system they work within may fall within the regulatory liminal space, which is to say that they may not land squarely within the perceived remit of any one regulator.

Threats to patient safety in relation to the discharge process may experience a similar fate and therefore not elicit an appropriate regulatory response. For example, at the start of 2020 (prior to the COVID-19 pandemic taking hold in the United Kingdom), the Royal Cornwall Hospitals NHS Trust informed staff that patients should be discharged early to reduce overcrowding. The memo sent to staff called the risk to patients ‘proportionate’ despite the likelihood ‘that some of these patients will be readmitted or possibly come to harm’.¹⁰¹ Requiring clinicians to discharge patients in cases where it may be against their clinical judgement to do so may mean asking them to act in a manner contrary to their professional standards.¹⁰² One doctor queried the GMC’s stance upon this matter and reported the response as, ‘We always consider a concern raised with [us] on the specific facts of the case, taking into account the factors relevant to the environment in which the doctor is working’.¹⁰³ The doctor argued this response provided little reassurance.

This example reveals three key features of this liminal space. First, it is surrounded by ‘thresholds’ constructed by regulators and informed by their risk-based approaches (e.g. – does the risk threaten the achievement of their objectives, and if so, how severe will its impact be?).¹⁰⁴ Where an incident is not perceived as meeting the regulator’s threshold for action, the regulator is unlikely to respond. In the scenario above, the risk to patient safety *should* be situated within the remit of the systems regulators (it is a pressure arising from an under-resourced hospital) and within the remit of the professional regulators – for it is an issue likely to impact upon the ability of healthcare

100. Scottish Government, (2019), Improving General Practice Sustainability Group: 2019 Report, Available at: <https://www.gov.scot/publications/improving-general-practice-sustainability-group-2019-report/pages/1/> (accessed 1 June 2021). Annex B.

101. ‘Cornwall Hospital to Discharge Patients Early Despite Saying it may be Harmful’, *The Guardian* 14 January 2020. <<https://www.theguardian.com/society/2020/jan/14/cornwall-hospital-to-discharge-patients-early-despite-risks>> (accessed 1 June 2021).

102. D. Oliver, ‘The Risks of Discharging Patients Early against Doctors’ Judgment’, *British Medical Journal* 368 (2020).

103. Op. cit. p. 2.

104. Black and Baldwin, ‘Really Responsive’; Needs citation.

professionals to act in accordance with their professional standards.¹⁰⁵ Yet the GMC has not commented further on this incident, nor has the CQC or NHSE/NHSI – all of whom should be able to recognise the potential impact upon patient safety and their ability to achieve their statutory objectives in this regard. Secondly, there is a lack of regulatory structure within the liminal space – which may explain why no regulator is taking the lead on addressing the patient safety issue identified above. Thirdly, there is no clear authority figure present within it driving regulators to act. This article now turns its attention to the impact this liminal space has on actions undertaken by those within the regulatory arena. These actions are intended to improve patient safety during the discharge process.

Liminal objects within hospital discharge regulation

Acknowledging that liminality is typically applied to people, Taylor-Alexander and colleagues argue that it can also be applied to ‘things’ – doing so enables a richer understanding of the relations between people and their surroundings.¹⁰⁶ For, as with humans, things can also pass through periods of transition; the authors provide an example of health research protocol documents to demonstrate this. The research protocol document undergoes ‘multiple transitory passages and transformations, marked by both uncertainty and the guiding (or editing) hand of a gatekeeper or steward to lead it through the passage(s) towards approbation’.¹⁰⁷ In the same way that liminality involves a Representative of Order who guides a person through transformation, regulatory actors may guide objects, such as these protocols, through the liminal phase.

It is argued here that a Representative of Order is key to preventing objects becoming stuck in a liminal state within the hospital discharge regulatory arena. ‘Objects’ in this context is used to refer to the outputs of any actor within this regulatory space that is intended to improve patient safety during the discharge process. These objects often stem from patient safety incidents. For example, a hospital discharge-related PSI may result in one or more of the following actions: a hospital may instigate its own investigation; a patient may make a complaint to a regulatory body or the PHSO; and (where a patient has died) a coroner may investigate and produce a prevention of future death (PFD) report.¹⁰⁸ Incidents may also trigger an investigation by the Health and Safety Investigation Branch, a body which aims to improve patient safety through investigations without assigning blame or liability.¹⁰⁹ As highlighted earlier, patients may also share their experiences with HE and charities, such as the British Red Cross. These actions often result in the production of a report detailing how improvements could be made. These reports are ‘objects’ that are vulnerable to failing to cross any of the regulatory thresholds surrounding them that would enable the prevention of such future incidents through learning and proportionate regulatory responses.

105. Moore, ‘Leaving Hospital’.

106. S. Taylor-Alexander, ‘Beyond Regulatory Compression’.

107. Op. cit. p. 159.

108. Under the Coroner and Justice Act 2009, coroners have a duty to make these reports.

109. Available at: <https://www.hsib.org.uk/> (accessed 1 June 2021).

Two of these objects, the PHSO report into unsafe hospital discharges¹¹⁰ and the 2019 British Red Cross report into safety during hospital discharges,¹¹¹ will now be used to illustrate the argument that a Representative of Order is key to improving safety in this space.

The PHSO report into unsafe discharges highlights failings which are indicative of the nature of complaints it receives regarding unsafe hospital discharge. It asks for the Department of Health and Social Care (DHSC) and NHS to establish the scale of the problems and to understand the causes, 'so that others do not have to experience such avoidable and unnecessary suffering'.¹¹² The report is intended to influence other actors within the hospital discharge regulatory arena, but to do so it needs to be visible. The House of Commons' Standing Orders¹¹³ ultimately bring about this visibility. The Orders direct the manner in which House of Commons' public business is conducted; they are a regulatory requirement. These Orders state that one of the functions of the Public Administration and Constitutional Affairs Committee (PACAC) is to examine reports by the PHSO. The PACAC may then use these reports to hold the government to account.¹¹⁴ In response to the PHSO report on unsafe discharges, the PACAC held an inquiry to understand the scale of the highlighted problems, to assess the measures for improving discharge practice and to clarify responsibilities and accountabilities across Government for ensuring implementation of the improvements and the safety of discharge processes.¹¹⁵ By triggering such action, this regulatory requirement is acting as a Representative of Order, leading the report through its transformation from a passive object into an 'active subject-object'.¹¹⁶ In this final state, the report is able to exert its intended influence within the hospital discharge regulatory arena.

In cases where concerns are raised by patient organisations, or charities, this role is unfulfilled by any legal or regulatory framework, and this increases the risk of reports which are intended to be active-subject objects becoming stuck in a liminal state. In failing to transition from passive object to active-subject object, these reports become a 'stagnated presence' within the hospital discharge regulatory arena.¹¹⁷

For example, the 2019 British Red Cross report documents patients' experiences of being discharged from hospital, presumably shared by patients hoping to improve the

110. PHSO, 'Investigations into Unsafe Discharge'.

111. British Red Cross, 'Home to the Unknown'.

112. PHSO, 'Investigations into Unsafe Discharge', p. 3.

113. HoC Standing Orders Public Business 2019 at 146(1).

114. Available at: <https://committees.parliament.uk/committee/327/public-administration-and-constitutional-affairs-committee/role/> (accessed 1 June 2021).

115. Fifth Report from the Public Administration and Constitutional Affairs Committee HC 97 (2016-17).

116. Taylor-Alexander, 'Beyond Regulatory Compression'.

117. This term is borrowed from Boyacıoğlu's writing on beliefs surrounding revenants in medieval Britain. These revenants, trapped between the living and the dead, are 'stagnated presences'. For a fascinating (somewhat off topic) read on this matter see E. Boyacıoğlu, 'The Revenant on the Threshold', *Folklore: Electronic Journal of Folklore* 62 (2015), pp. 7–36.

experience for future patients. The report states that, 'being clearer about the relationship between what happens in hospital and what happens when people go home – seeing through patients' eyes how it feels when they walk back through their front door – can only help patients and professionals alike'.¹¹⁸ Such a report, intertwined with human experience and the potential to cross spatial-temporal boundaries, should have the potential to be a powerful regulatory tool. However, there is no evidence to indicate that the findings have been heard by any of the statutory regulators. This is important because statutory regulators are the ones in a position to check whether recommendations have been received by healthcare providers and/or implemented.

As there is no regulatory framework or organisation responsible for acting on these recommendations, the report is not delivered through the liminal phase and transformed into an active subject-object where it can influence behaviours and become an actor in the hospital discharge regulatory arena. Instead, it is stuck as a stagnated presence, unable to reintegrate into the regulatory space and have the impact intended by its creators. Any learning that could be gained from previous patients' experiences of discharge thus goes unheeded, resulting in missed opportunities for improvement. By contrast, active subject-objects within this space play important roles in not only highlighting unsafe discharges but also in recommending ways that these can be overcome and in compelling a response. Representatives of Order are fundamental to preventing objects becoming stuck. In this liminal space, where regulatory structure is missing, a Representative of Order is needed to guide these liminal objects out of their status as a stagnated presence and into their role as active-subject object; doing so will increase the ability of regulators to keep patients safe during discharge.

The following section examines the recommendation proposed by the IMMDS review to create a PSC. This role has now been established in the MMD Act. The purpose of this examination is to consider whether the PSC could act as a Representative of Order and ultimately improve patient safety during the discharge process.

The Patient Safety Commissioner

As mentioned at the start of this article, the purpose of the IMMDS review was to consider how the healthcare system in England responds when concerns are raised about harmful side effects from medicines and medical devices. It focussed specifically upon hormone pregnancy tests, sodium valproate and pelvic mesh implants.¹¹⁹ The review further considered how future responses could be quicker and more effective, and how the patient voice could be strengthened to help build a system that listens to patients and acts promptly, with compassion and in a proportionate manner.¹²⁰ The review argues,

118. British Red Cross, 'Home to the Unknown', p. 8.

119. IMMDS Review, 'First do no Harm'.

120. *Op. cit.*, p. 186.

we do not need another regulatory body in an already crowded field. But we do need a new voice, with statutory powers, to talk and act from the perspective of the patient, to encourage the system to do what needs to be done and hold it to account'.¹²¹

As such, one of its recommendations, which shall be considered in-depth here, was the creation of a new PSC role.

The PSC as envisaged in the IMMDS review was to be independent and have a statutory responsibility to champion the value of listening to patients and promoting users' views in improving patient safety. They would be responsible for identifying steps needed to improve patient safety regarding the use of medicines and medical devices and for encouraging other organisations to act. It was intended that the PSC would be a means of holding the system to account, and they would be accountable to Parliament through the Health and Social Care Select Committee.¹²²

The review envisaged that a core set of statutory principles, to be developed by the PSC, would support the PSC in determining the appropriate response to any issues raised. It was anticipated that the Commissioner would lead reviews and investigations, which would result in advice and recommendations. Reviews would potentially include thematic investigations of systemic issues; in-depth inquiries into specific patient safety concerns not undertaken by another organisation; and assessments of an organisation's patient safety performance, against the principles.¹²³ The resulting advice could be in the form of specific recommendations to address the identified concerns, encouraging other bodies to implement recommendations and highlighting concerns about failures to improve patient safety to the Secretary of State for Health and in public reports.¹²⁴

Although the review suggested the PSC would be prevented from investigating individual cases (for this would duplicate the work of the PHSO), it stated that the PSC would be open to receiving concerns from patients and other members of the public, as well as patient representative organisations. This is because the PSC was expected to have a higher public profile than other complaints bodies, and it was proposed that direct reports from patients could be relayed to other organisations if appropriate. In such cases, the PSC would retain an interest in how the reports are handled, and what the outcomes are.¹²⁵ It was further proposed that the PSC would be responsible for obtaining relevant patient safety information from other organisations to assist their primary functions. This would be, for example, through making arrangements to receive reports relating to medicine safety from the National Freedom to Speak Up Guardian.¹²⁶ The report did

121. Op. cit., p. 10.

122. Op. cit., p. 200.

123. IMMDS Review, 'First do no harm', p. 206.

124. Op. cit. p. 206.

125. Op. cit. p. 206.

126. This role was created in response to recommendations made in Francis' report "The Freedom to Speak Up" (2015). The recommendations followed findings that NHS culture failed to support workers to speak up, and patients/staff suffered as a result. For further information see Available at: <https://nationalguardian.org.uk/about-us/> (accessed 1 June 2021).

not propose giving the PSC ‘more wide-ranging regulatory powers’, stressing instead that the role is that of a champion – amplifying patients’ voices and delivering systemic improvements in patient safety.¹²⁷

The new MMD Act confirms that the PSC role will be established and have statutory powers. Although lacking the fine detail provided in the IMMDS review, the role is generally reflective of that proposed by the review. It states that the PSC’s core duties are to promote the safety of patients with regard to the use of medicines and medical devices and to promote the importance of the views of patients and other members of the public in relation to the safety of medicines and medical devices.¹²⁸ In doing so, the PSC must prepare and publish a set of governing principles and must take reasonable steps to involve patients in discharging their core duties.¹²⁹ The PSC may make reports, and request and share information with relevant persons. In such cases, relevant persons must comply, provided that doing so does not contravene data protection legislation.¹³⁰ The MMD Act does not state who the PSC is to be accountable to; this detail is likely to follow in subsequent regulations.¹³¹

As can be seen from the summary above, the PSC will be responsible for listening to patients and identifying the steps required to improve patient safety regarding the use of medicines and medical devices. By focussing the role of the PSC solely on medicines and medical devices, the opportunity to improve patient safety with regard to *processes*, such as hospital discharges, appears to have been missed. As I will now argue, the remit of the PSC should be expanded to include such processes. This is proposed because the risk of harm posed by hospital discharges has not been adequately addressed by statutory regulators, despite numerous reports (as highlighted in section two) having raised the issue. Liminality, employed here as an exploratory lens, has shed light on the nature of this regulatory problem – namely that objects intended to influence action fail in this endeavour. Expanding the remit of the PSC in this way will amplify the voices of patients harmed during discharge – a complex process involving interactions between a healthcare system and the professionals working within it. If healthcare is to truly become safer, holding the system to account and listening to patient’s safety experiences regarding all aspects of their healthcare journey are necessary.

This article envisages that the PSC could function as a Representative of Order – a figure able to guide objects and persons through their liminal state and assist actors within the regulatory space to navigate the liminal space between them. Before moving on to consider how the PSC might function as a Representative of Order, let us now turn to another individual who fulfils the Representative of Order role within the patient safety field as part of their remit – the Chief Coroner. Doing so will not only demonstrate

127. Op. cit., p. 209.

128. Medicines and Medical Devices Act 2021, section 1(2a).

129. Op. cit, schedule 1.

130. Op. cit, schedule 1.

131. DHSC, ‘Factsheet: Patient Safety Commissioner’, Available at: <https://www.gov.uk/government/publications/medicines-and-medical-devices-bill-overarching-documents/medicines-and-medical-devices-bill-patient-safety-commissioner> (accessed 1 June 2021).

the benefits such figures can bring to patient safety but also provide valuable insight into how the PSC role might be strengthened.

The Chief Coroner as a Representative of Order

The Chief Coroner acts as a centralised figure¹³² within the coronial system in England and Wales and is responsible for setting national standards within the coronial system, and overseeing the implementation and development of reforms. The creation of this role was triggered by the Inquiry into the actions of Harold Shipman, a general practitioner convicted of murdering 15 patients in 2000.¹³³ Among multiple systemic failings, the inquiry identified several weaknesses within the coronial system and recommended fundamental reform, led by a Chief Coroner. Ten years later, the new Coroner and Justice Act 2009 ('the 2009 Act') was implemented, bringing with it the new role of the Chief Coroner (the first one came into post 3 years later).¹³⁴

As will now be demonstrated, through the lens of liminality, we can see how the Chief Coroner serves as a Representative of Order to keep patients safe. Regarding death and bereavement, van Gennep says:

in some cases the transitional period of the living is a counterpart of the transitional period of the deceased, and the termination of the first sometimes coincides with the termination of the second – that is, with the incorporation of the deceased into the world of the dead.¹³⁵

The salient point here is that bereavement is a rite of passage.¹³⁶ The Shipman Inquiry recognised this where it noted that the family of a deceased person value being involved in registering the death of their loved one.¹³⁷ In a similar vein, where the cause of death is unknown, the bereaved may find themselves in a liminal state, unable to reintegrate in society in their new role. It is often important for the bereaved to know that steps have been taken to protect others from dying in similar manners,¹³⁸ and in this sense, PFD reports play a role in guiding them through the liminal stage of bereavement.

132. J. Moore, *Coroners' Recommendations and the Promise of Saved Lives* (Cheltenham: Edward Elgar Publishing, 2016).

133. J. Smith, *The Shipman Inquiry Third Report: Death Certification and the Investigation of Deaths by Coroners* (London: The Stationary Office, 2003).

134. Chief Coroner, (2018) 'Report of the Chief Coroner to the Lord Chancellor: Fifth Annual Report: 2017-2018', Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/764720/report-of-the-chief-coroner-lord-chancellor-2017-18.pdf (accessed 1 June 2021).

135. van Gennep, 'Rites of Passage', p. 147

136. Hunter observes bereavement-related rituals are so integrated with death rituals, bereavement is rarely considered its own rite of passage (J. Hunter, 'Bereavement: An Incomplete Rite of Passage', *OMEGA* 56 (2008), pp. 153–173.

137. Smith, 'The Shipman Inquiry Third Report'.

138. NHS Resolution, (2018), 'Learning from Suicide-Related Claims: A Thematic Review of NHS Resolution Data', Available at: <https://resolution.nhs.uk/resources/learning-from-suicide-related-claims/> (accessed 1 June 2021); INQUEST, (2020), 'Submission to the

Under the 2009 Act, coroners have a duty to make these reports (also known as Regulation 28 Reports) and to send them to the Chief Coroner and ‘every interested person who in the coroner’s opinion should receive it’.¹³⁹ PFD reports raise concerns arising from coroners’ investigations on actions that should be taken to prevent similar future deaths, and recipients have 56 days to respond.¹⁴⁰ They reflect the circumstances leading up to the person’s death and are key to preventing others from dying in similar circumstances. All reports are published online by the Chief Coroner and so are publicly accessible. Through acting as a Representative of Order, the Chief Coroner is able to ensure that PFD reports do not get stuck in a state of liminality. Firstly, he may send a copy of the report to any person who he believes may find it useful or of interest,¹⁴¹ and secondly, he has access to all reports which should enable regular analysis to be undertaken so that common themes can be disseminated nationally among relevant and interested parties. Essentially, the creation of a Chief Coroner reduces the likelihood of both PFD reports and bereaved people becoming stuck in liminal states. In the case of PFD reports, the Chief Coroner is able to ensure they cross temporal–spatial boundaries to influence the safety of others. Knowing that lessons learned from a loved one’s death will safeguard others may also support bereaved people’s journey through the grieving process. However, as will be explored in the following section, there is scope for the Chief Coroner’s role in this regard to be improved. Reflecting on the efficacy of this particular Representative of Order will enable the PSC to avoid similar difficulties.

The Patient Safety Commissioner as a Representative of Order

In a similar manner to the way in which the creation of the Chief Coroner role is starting to result in increasingly successful navigation of the liminal space within the disjointed coronial system,¹⁴² the PSC could support actors within the context of the hospital discharge regulatory arena. The PSC, with the extended remit over processes argued for herein, will have a high public profile and be empowered to receive, and to actively seek, information pertaining to patient safety from a vast range of sources. This should result in them having powerful, all-encompassing insight into safety concerns across the entire healthcare system.

To recap briefly on the points made in third section, the liminal space within the hospital discharge regulatory arena is present in part due to multiple regulators and the related challenge they face in forming a unified understanding and prioritisation of the risk posed by hospital discharges.¹⁴³ Actions then taken by actors with the regulatory arena to improve safety during discharges (often the production of a report) risk

Justice Select Committee Inquiry into the Coroner Service’, Available at: <https://www.inquest.org.uk/Handlers/Download.ashx?IDMF=e404f863-cdfb-47b6-8e34-a65118520331> (accessed 1 June 2021).

139. Coroner and Justice Act 2009, para 7, Schedule 5.

140. The Coroners (Investigations) Regulations 2013, Regulation 29.

141. Op. cit., Regulation 28.

142. Chief Coroner, Fifth annual report.

143. Moore, ‘Leaving Hospital’.

becoming a stagnated presence, unable to cross regulators' thresholds or influence the behaviour of actors within the regulatory arena. These two issues need resolving to improve patient safety during the discharge process.

Navigating the liminal space

With regard to this first issue, by acting as a centralised figure, the PSC will be able to assist regulators in developing a uniform response to the patient safety risks posed by hospital discharges. Although this might not directly translate into risk being prioritised in the same manner, it creates room for discussion on multi-actor approaches to addressing the problem. A unified understanding of the risk will not necessarily reduce the presence of the liminal space within; however, the presence of these spaces should not be thought of as undesirable. By acting as a Representative of Order, the PSC could be in a position to encourage regulators to engage within this liminal space. In this regard, the PSC would be embracing the role of stewardship, which Laurie and colleagues define as 'guiding others with prudence and care across one or more endeavours – without which there is risk of impairment or harm—and with a view to collective betterment'.¹⁴⁴ Laurie and colleagues note that within the context of health research regulation, regulatory stewardship plays a central, yet often invisible role.¹⁴⁵ Regulatory actors within the hospital discharge arena may already be involved in this type of stewardship; the GMC for example provides ethical advice to individual doctors upon request to assist them in their efforts to adhere to professional standards.¹⁴⁶

Importantly, Laurie and colleagues stress that fulfilling the role of regulatory stewardship should not fall to any single actor, as this would risk the role being seen as someone else's responsibility.¹⁴⁷ This is a valid concern – and as such, this article does not see the PSC as being the only actor within this regulatory arena to be charged with this role. Rather, they should encourage other regulators to collaboratively engage in this role within the liminal space.

Returning to the notion of *communitas* discussed in the third section, although *communitas* cannot be artificially created within a liminal space, such spaces can still have productive potential.¹⁴⁸ The PSC as a Representative of Order could help regulators to utilise this potential, while recognising that such spaces might develop a dynamic of their own.¹⁴⁹ For example, within the research and policy context, Laurie cites the emerging use of regulatory sandpits (also known as sandboxes)¹⁵⁰ as an example of how this

144. Laurie, 'Regulatory Stewardship', p. 338.

145. Op. cit. p.338.

146. See, for example, GMC 'Contact Us', Available at: <https://www.gmc-uk.org/contact-us> (accessed 1 June 2021).

147. Laurie, 'Regulatory Stewardship', p. 338.

148. Laurie, 'Liminality and the limits of law', p. 60.

149. Op. cit. p. 60.

150. Sandboxes started in the financial industry as a framework set up by the regulator to allow testing of innovations in controlled environments under the regulator's supervision. It is argued they have the potential to shift the relationship between regulators and financial

potential could be utilised.¹⁵¹ Sandboxes involve regulators collaborating with other parties (such as service users and healthcare providers) on an equal footing (in a manner similar to what might happen where *communitas* arises), to generate and develop solutions to problems. The CQC has recently adopted the idea of the regulatory sandbox to provide a space where providers can work alongside them to consider new ways of working that fit with regulation.¹⁵² If the PSC facilitates regulatory bodies engaging in the liminal space around them, novel regulatory solutions to the complex safety problem posed by hospital discharges may be reached. The PSC would, however, need to be cognisant of legal requirements which may impede regulators' ability to be creative and agile in seeking solutions. For example, speaking on how legal requirements restrict regulatory agility, the GMC's chief executive said the restrictive legal framework prevents overseas doctors being rapidly registered to work in the United Kingdom despite severe shortages in the United Kingdom. He stated that the GMC wishes to provide additional resources into preventing medical errors, but instead is compelled by legislation to spend the majority of its time processing complaints, 'the majority of which come to nothing'.¹⁵³

Guiding liminal objects

As demonstrated by the example of the Chief Coroner and PFD reports, a Representative of Order has the ability to prevent objects becoming stuck in a liminal state. This is through having oversight of all PFD reports, being able to analyse them for common themes and raise concerns with appropriate parties to address safety issues. It must, however, be noted that INQUEST have recently highlighted that regular analysis of themes is not currently happening.¹⁵⁴ This is a failure on behalf of the Chief Coroner, for it is an essential part of enabling the reports to fulfil their intended roles as a tool to influence the experiences of others and prevent future deaths. The Chief Coroner acknowledged the importance of PFD reports in his fifth annual report and said additional staffing would enable the trends in reports and the responses to them to be drawn together.¹⁵⁵ The lesson here when establishing the PSC is that sufficient funding and resource must be provided in order for them to perform their role satisfactorily.¹⁵⁶

services providers towards a more open and active dialogue. See I. Jenik and K. Lauer (2017), 'Regulatory Sandboxes and Financial Inclusion', Available at: <https://www.cgap.org/sites/default/files/Working-Paper-Regulatory-Sandboxes-Oct-2017.pdf>

151. Laurie, 'Liminality and the limits of law', p. 60.

152. Available at: <https://www.digitalhealth.net/2020/02/cqc-publishes-report-into-its-first-regulatory-sandbox-pilot/> (accessed 1 June 2021).

153. C. Massey, 'Regulation Overhaul Urgently Needed', Available at <https://www.gmc-uk.org/news/news-archive/regulation-overhaul-urgently-needed> (accessed 1 June 2021).

154. INQUEST, Submission to the Justice Select Committee Inquiry.

155. Chief Coroner, Fifth annual report, p. 19.

156. The IMMDS review proposes that the Commissioner's work is supported by government grant-in-aid funding (p. 210)

It is envisaged that in the case of hospital discharges, where reports such as those mentioned earlier in this article are produced to highlight the risks to patients, the PSC would be able to direct them to regulatory bodies to act upon. This would prevent objects from becoming stuck in a liminal state and enable them to reach their intended potential in influencing change. However, if this advice of the PSC is to be heeded, it is important that the PSC is aware of regulators' remits and their legal limitations. Otherwise, advice will likely be met with pushback. Research by Moore into why coroners' recommendations in New Zealand were rejected by organisations found that it was important for organisations to be correctly identified and targeted; organisations did not appreciate being a 'convenient PO box'.¹⁵⁷

The PSC as proposed will not have any direct enforcement powers. This means that although advice can be provided to regulators and other actors within the safe discharge space, if actors are reluctant to engage in spaces beyond their remit, then the only recourse available to the PSC is to escalate concerns to the Health Secretary. It is anticipated that this is unlikely to translate into any further action being taken against regulators, which risks safety issues at discharge remaining unaddressed. It is therefore critically important that the PSC works alongside regulators and is established as an authority figure to reduce the likelihood of this happening.

Conclusion

This article has used the anthropological concept of liminality as a lens through which to explore and identify regulatory challenges in addressing patient safety issues related to hospital discharges. This has brought into focus the liminal space that exists among regulatory bodies within the hospital discharge regulatory arena. The liminal space occurs because hospital discharges can be complex processes where safety depends upon the quality and availability of the healthcare system and the actions of many healthcare professionals. This means the regulatory arena contains numerous statutory regulators with varying thresholds for action – making it difficult for regulators to establish a unified understanding and prioritisation of the risk facing patients. Furthermore, actions to improve safety in this regard often become stagnated presences, unable to have their intended impact within the regulatory arena.

Liminality in itself does not present a solution to the patient safety problem posed by discharges. However, by using it as a lens through which to view the regulatory arena, it has brought to light the critical need for a Representative of Order to ensure that recommendations regarding patient safety during discharge are recognised by regulators. This article has cast the Patient Safety Commissioner as a candidate to fulfil this role.

If the remit of the PSC were extended, as called for in this article, the PSC could be in a position to aid regulators in developing a uniform understanding of the risk posed to patient safety by hospital discharges. This would result from the PSC being in a position to listen to patients and obtain evidence from a wide variety of sources regarding what goes wrong with the discharge process. Armed with this knowledge, the PSC could

157. Moore, *Coroners Recommendations*, p. 145.

advise regulators and encourage them to engage within the liminal space around them – presenting the opportunity for solutions to this complex safety problem to be uncovered. Furthermore, the PSC would be able to ensure that objects produced by actors with the intent of improving discharge safety, such as reports into unsafe discharges, would become active subject–objects. This would be achieved through the PSC ensuring that appropriate regulatory bodies are aware of the findings and providing advice on how they may be able to respond.

In summary, through using the lens of liminality, this article has demonstrated not only the importance of a PSC championing patients' voices but also its potential to bridge regulatory gaps. The impact this could have on improving patient safety should not be underestimated, particularly when it could improve the safety of the hospital discharge process for patients.

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